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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,711	04/18/2006	Kunio Ishikawa	TSUZ 200026US01	8622
27885	7590	12/07/2010		
FAY SHARPE LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115			EXAMINER COTRONEO, STEVEN J	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/07/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,711	Applicant(s) ISHIKAWA ET AL.	
	Examiner STEVEN J. COTRONEO	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-4, 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4 and 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 6, 7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kadoma et al. (JP 11180705 see machine translation provided in previous action) in view of Breitscheidel et al. (US 2004/0198909).

Kadoma et al. discloses a method of producing a bone substitute material **(paragraph 1 “biocompatibility, are used as a bone, a dental restorative material”)** in the form of a block predominantly composed of carbonate apatite for medical use **(Claim 5 “porous apatite” (from claim 1) a solid compound ... uses calcium carbonate”)**, which comprises the step of forming carbonate apatite by contacting a block of calcium compound **(Claim 5)** with a phosphate-containing solution (diammonium hydrogenphosphate solution and **claim 1, solution including phosphoric acid**), wherein the calcium compound block contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight of the calcium compound block (discloses using a block), wherein at least one of the calcium compound block and the phosphate solution contains a carbonate group (paragraph 15 "calcium carbonate system" **and claim 5**), and wherein the method does not include any sintering step (paragraph 4, “without passing through a

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high temperature process," i.e. sintering). (With out the step of sintering there can not be powders... sintering is the process of using powder to form a solid... Kadoma et al. uses a block put into a solution). The block is immersed into a phosphate containing solution (paragraph 28). The block is a foam block (claim 1, "porous"). The calcium can be a calcium sulfate (paragraph 6).

Kadoma et al. discloses the claimed invention except for the calcium being from an artificial calcium source. Kadoma discloses using limestone as a calcium carbonate source. Breitscheidel et al. discloses using natural limestone and synthetic calcium carbonate are functionally equivalent (paragraph 53) because both result in a calcium carbonate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to for the calcium source to be an artificial calcium source, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Kadoma discloses the claimed invention except for the phosphate solution being an ammonium carbonate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ammonium carbonate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Kadoma discloses the claimed invention except for the phosphate solution being a tricalcium phosphate. It would have been obvious to one having ordinary skill in the

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art at the time the invention was made to tricacium phosphate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 8, 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kadoma et al. (JP 11180705 see machine translation provided) in view of) in view of Breitscheidel et al. (US 2004/0198909) in view of Hall (Hall, Brian. "Experimental investigation on Pore Size and Pore Distribution," Bone: Fracture Repair and Regeneration. Volume 5. 1991. CRC Press, Inc. pages 161-162. Accessed through Google books on 7/15/09. PDF of relevant pages provided. In the office action dated 7/20/2009).

Kadoma in view of Breitscheidel discloses the claimed invention except for the pore size being between 50 and 1000 micrometers. **Kadoma does disclose a porous material (claim 1) and a material to replace or restore bone (paragraph 1).** Hall discloses the most appropriate pore size for bone implants to be between 50 and 400 m to allow for osteon formation (i.e. it teaches the proper bone porosity for replacing bone). It would have been obvious to one having ordinary skill in the art at the time the invention was made for the pore size being between 50 and 1000 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 9/30/2010 have been fully considered but they are not persuasive. In response to applicant's argument that Kadoma and Breitscheidel is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both are directed to sources of naturally occurring calcium carbonate.

The applicant also argues that Kadoma does not suggest a block having no powders. The examiner respectfully disagrees. Kadoma as pointed out in the previous office action dated 7/6/2010 discloses in paragraph 4 that there is no sintering therefore there can be no powders.

The applicant also argues that having a porous product does not mean there is a porous starting material. The examiner respectfully disagrees. If the solid starting material was not porous there is no step in Kadoma that teaches how the product would become porous, therefore the block must be porous.

The applicant also argues that there is no suggesting that teaches the use of an ammonium carbonate. The examiner respectfully disagrees. To get the final mixture disclosed by Kadoma only so many different solutions can be used to create a carbonate apatite therefore it would be obvious to try the varying solutions.

With regard to the Hall reference the applicant argues that there is no suggestion that the pores of a metal implant would be similar to pores of a bone material implant. The examiner respectfully disagrees. Hall discusses the pore size necessary for bone growth. There should not be difference between materials because the pore size is related to the ability of bone to grow into the implant. Osteonal size of bone is the limiting factor not the material when determining the pore size.

With respect to claim 4 the applicant argues that Kadoma is produced with pulverized materials. The examiner respectfully disagrees. Example 1 of Kadoma discloses using a 1 to 1.5mm block and does not disclose that the block is pulverized.

The rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./
Examiner, Art Unit 3733

/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733